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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/724,564	11/26/2003	Wayne Edward Beimesch	414130	9670		
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LATHROP & GAGE LC	ROGERS, DAVID A					
2345 GRAND AVENUE	ART UNIT		PAPER NUMBER			
SUITE 2800	2856					
KANSAS CITY, MO 64108						
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,564	BEIMESCH, WAYNE EDWARD	
	Examiner	Art Unit	
	DAVID A. ROGERS	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 January 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 23-34 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 23-34 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 16 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/24/07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 4,930,906 to Hemphill.

Official notice was taken in a previous office action that aluminum foil is a material that inherently does not release significant amounts of volatile organic compounds (VOCs). The applicant did not traverse this official notice. Rather, the applicant agrees with this statement. See page of the response filed 9/18/07:

With respect to Claim 23, Applicant recognizes that the Examiner's official notice that aluminum foil is a material that does not release significant amounts of volatile organic compounds (VOCs).

Therefore, this is now factual prior art.

With regard to claims 23 and 25 the phrase "for measuring the volatile organic compounds of a substance" is not being affording any patentable weight. This phrase amounts to how the kit is to be used and does change or otherwise impact the structure of the kit. As the applicant is fully aware a recitation of the intended use of the claimed invention must result in a

structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With regard to claim 24 the phrase “for measuring the volatile organic compounds of a substance produced in a process system having emissions” is not being affording any patentable weight. This phrase amounts to how the kit is to be used and does change or otherwise impact the structure of the kit. As the applicant is fully aware a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Hemphill discloses an enclosed bag (reference item 10) and having instructions (reference items 18 and 20). Hemphill’s bag, being foldable, is also inherently collapsible in that it is formed of thin plies of materials. The enclosed bag also has a maximum fill line (reference item 19). This bag, when sealed, would have a headspace above the maximum fill line. Hemphill’s bag is formed of a multiply construction. The inner layer (reference item 13) is formed of aluminum. The intermediate layer (reference item 11) is formed of polyethylene. The outer layer (reference item 13) is formed of paper.

According to Hemphill the outer paper layer is provided to “protect an individual from being burned by the hot grease.” See column 4 (lines 26-28). It is considered obvious to eliminate the outer paper layer when protection from hot grease is not an issue. For example, the bag could be used to store cooler materials, including cold grease, so that burning is not design consideration. See also MPEP §2144.0 4:

A. Omission of an Element and Its Function Is Obvious If the Function of the Element Is Not Desired

Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to a method for inhibiting corrosion on metal surfaces using a composition consisting of epoxy resin, petroleum sulfonate, and hydrocarbon diluent. The claims were rejected over a primary reference which disclosed an anticorrosion composition of epoxy resin, hydrocarbon diluent, and polybasic acid salts wherein said salts were taught to be beneficial when employed in a freshwater environment, in view of secondary references which clearly suggested the addition of petroleum sulfonate to corrosion inhibiting compositions. The Board affirmed the rejection, holding that it would have been obvious to omit the polybasic acid salts of the primary reference where the function attributed to such salt is not desired or required, such as in compositions for providing corrosion resistance in environments which do not encounter fresh water.). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) (Omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious expedient).

With regard to claim 23 (lines 5-7) the claimed bag is formed of materials that do not release significant amounts of VOCs. A review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a polyethylene outer layer. Therefore,

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aluminum and polyethylene are materials that do not release significant amounts of VOCs. The bag of Hemphill, when the paper layer is omitted, is also formed of aluminum and polyethylene and, therefore, will also be formed of materials that do not release significant amounts of VOCs.

With regard to claim 24 (lines 6-8) the claimed bag is formed of materials that can be safely stored at the exit temperature of a process system. A review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a polyethylene outer layer. Therefore, aluminum and polyethylene are materials that can be safely stored at the exit temperature of a process system. The bag of Hemphill, with or without the paper layer, is also formed of aluminum and polyethylene and, therefore, will also be formed of materials that can be safely stored at the exit temperature of a process system.

With regard to claim 25 (lines 5-7) the claimed bag consists of two layers, one being an impermeable inner layer and one being a polymer outer layer. A review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a polyethylene outer layer. The bag of Hemphill, without the paper layer, will consist of two layers wherein the inside layer (reference item 13) is the vapor impermeable aluminum layer and the outer layer (reference item 11) is made of a polyethylene polymer.

With regard to claim 32 (lines 3-5) the claimed bag has a wall consisting of an inner liner and an outer liner that do not release significant amounts of VOCs. A review of the applicant's written description shows that the sole disclosed embodiment for the bag is one formed of an aluminum inner layer and a polyethylene outer layer. Therefore, aluminum and polyethylene are materials that do not release significant amounts of VOCs. The bag of Hemphill, without the paper layer, will have a wall consisting of two liners wherein the inside aluminum liner (reference item 13) and the outer polyethylene liner (reference item 11). The bag of Hemphill, when the paper layer is omitted, will also be formed of materials that do not release significant amounts of VOCs.

In all Hemphill teaches a kit that meets the structural limitations of the applicant's claims. Hemphill, however, does not teach specific instructions with regard to sampling and analyzing.

In the precedential decision *In re Ngai*, 70 USPQ 2d 1862, the Court of Appeals for the Federal Circuit (CAFC) reviewed a situation clearly analogous to the applicant's claims. In *Ngai et al.* a kit was claimed was claimed as follows (emphasis added):

19. A kit for normalizing and amplifying an RNA population, said kit comprising instructions describing the method of claim 1 and a premeasured portion of a reagent selected from the group consisting of: oligo dT biotinylated primer, T7 RNA polymerase, annealed biotinylated primers, streptavidin beads, polyadenyl transferase, reverse transcriptase, Rnase H, DNA pol I, buffers and nucleotides.

The CAFC analyzed Ngai *et al.*'s claim 19 and determined that the elements that formed the kit included a premeasured portion of reagent and instructions on how to use the reagent. The cited prior art was a kit having a 10X buffer and specific instructions on how to use the 10X buffer. In referring to *In re Gulack*, 703 F.2d 1381 [217 USPQ 401] (Fed. Cir. 1983), the CAFC stated:

"This case [Ngai], however, is dissimilar from *Gulack*. There the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. Here, addition of a new set of instructions into a known kit does not interrelate with the kit in the same way as the numbers interrelated with the band. In *Gulack*, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product. As the *Gulack* court pointed out, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." *Id.* If we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product."

The CAFC affirmed the Board of Patent Appeals and Interferences (BPAI) and concluded that Ngai *et al.*'s claimed kit was anticipated by the prior art (the 10X buffer with instructions), despite the fact that Ngai *et al.*'s claim 1 method was distinct from the instructions in the prior art. In fact, the method of claim 1 was determined to be patentable over the prior art. The CAFC further concluded that Ngai *et al.*'s instructions merely taught how to use the reagent component of the kit (the 10X buffer). Specifically, the CAFC concluded:

"All that the printed matter does is teach a new use for an existing product."

and

"He [*Ngai*] is not, however, entitled to patent a known product by simply attaching a set of instructions to that product."

In the present application the instructions merely teach a different use for a known sealable bag. The applicant's claimed enclosed bag does not depend on the claimed instructions in order to function; i.e., the instructions do not enable the bag to hold a sample. Likewise, the claimed instructions do not depend on the bag in order to instruct someone how to sample. Therefore, the applicant's instructions do not enable any sealable bag from holding any material and only describe a process to store a sample in the bag and then to sample the headspace of the bag.

The applicant's claims for a kit comprising a bag and instructions to use the bag is clearly analogous to Ngai *et al.*'s kit having a known reagent (the 10X buffer) and instructions that taught how to use the reagent. The applicant's arguments with regard to how their instructions are not taught by the prior art, and, therefore, there can be no anticipation are also similar to those proffered by Ngai *et al.* However, both the BPAI and the CAFC unequivocally and unambiguously disagreed with that argument.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Hemphill in order to provide appropriate instructions on how to use the bag based on the fact that the

applicant's kit is known or otherwise obvious in the art as evidenced by Hemphill, and further in view of the CAFC's decision in *In re Ngai*.

Response to Arguments

3. Applicant's arguments with respect to claims 23-34 and filed 07 January 2008 have been fully considered but are convincing.

The applicant argues that Hemphill is not analogous art. The claims are directed to a kit whose sole structural element is a bag. Hemphill teaches a bag. It is analogous art. Applicant is referred to MPEP §2141.01(a):

Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

In the present application the claims are directed to a bag. Hemphill clearly discloses a bag. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The applicant then focuses their argument on a particular section of the Office's *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of the Supreme Court Decision in KSR International Co. v. Teleflex, Inc.* In particular the applicant attempts to show that obviousness has not been shown under one specific rational, namely:

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

The applicant, however, completely ignores other rationales that the *Guidelines* suggest. For example, the *Guidelines* also suggest the following as a valid rational under *KSR*:

(E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

In this particular application the removal of a single ply to make a two-ply bag is merely one solution from, at most, six possible arrangements of the plies from the bag of Hemphill. When one considers the removal of the outer ply then the total number of possible arrangement of plies is two. Another issue that the applicant is ignoring is the prior decisions of *In re Larson* and *In re Kuhle* (cited above). The Supreme Court decision, and the *Guidelines*, are consistent with the decisions of *Larson* and *Kuhle*, as well as the decision in *Ex parte Wu* (also cited above).

The applicant argues that the removal of the outer layer would not have been obvious in light of their use of the bag at high temperatures. However, a review of the claims of the applicant make no mention of what temperatures ranges are to be within the range of a "exit temperature of the process system". Furthermore, the motivation to remove the outer layer may not and need not be the same as the applicant's need. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of

the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID A. ROGERS whose telephone number is (571)272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David Rogers/
Examiner - Group Art Unit 2856

/Hezron Williams/
Supervisory Patent Examiner, Art Unit 2856